REMARKS

The claims have been rejected as a being in definite. The examiner suggests that the term "carnitine substance" is unclear regarding the term substance. Page 5 of the specification establishes clear metes and bounds for the expression carnitine substance and applicant therefore submits that this term is clear and definite in the context of the claimed subject matter.

The examiner has suggested that the term "simple" is a relative term that renders claim 65 indefinite. Applicant submits that the term "simple" in claim 65 (and others), being used in conjunction with a carbohydrate or sugar, would be well understood by those skilled in the art. Representative references setting forth the general understanding among those skilled in the art of the terms "simple carbohydrate" and "simple sugar" as the group of compounds composed of monosaccharides and disaccharides are attached.

The claims have been amended to remove other specific objections raised by the examiner.

All claims stand rejected under 35 USC 102 and/or 35 USC 103 over Davis et al, Pola, Bowles et al or Gross et al. Applicant offers the following comments on the cited references.

A key distinction of the claimed subject matter is the increase in carnitine retention in skeletal muscle, and the claims have been amended accordingly. The relevance of this is explained below in relation to each of the cited references.

Davis et al relates to the provision of a composition or complex (and related methodology), comprising DL-carnitine and/or L-carnitine with glycine to stimulate the absorption of carnitine (and glycine) across the intestinal wall.

This is very different to the present claimed subject matter which relates to increasing carnitine retention in skeletal muscle. The uptake of carnitine into skeletal muscle is a very different process, far removed from the absorption of carnitine across the gut wall. As set out in applicant's specification, simply increasing the amount of carnitine in the blood/plasma

(which would be the effect following the teaching in Davis et al) does not of itself result in an increase in carnitine retention in skeletal muscle. Carnitine does not readily enter the muscle compartment (even following dramatic elevation of blood/plasma carnitine concentration).

Moreover, the complex in Davis et al does not comprise an agent that acts to increase blood/plasma insulin concentration, which is a key feature of the present claimed subject matter as it is this that enables enhanced carnitine uptake into skeletal muscle and thus increased carnitine retention.

Glycine transport across the gut is via a mechanism that is very different to the sodium potassium mechanism for the entry of carnitine into the skeletal muscle compartment. Indeed, the glycine transport mechanism is not present in skeletal muscle tissue membrane.

Pola relates to the provision of a dietary supplement comprising a "carnitine substance" and ribose or its phosphorylated analogues.

The key distinction here is that ribose (or its phosphorylated analogues) does not stimulate insulin production, and therefore Pola does not disclose or suggest providing an agent to increase blood/plasma insulin concentration or stimulate insulin release in the body.

In Pola, all of the experimental data appears to relate to work done on heart muscle. It is well known to those skilled in the art that in contrast to skeletal muscle, heart muscle will inherently take up carnitine from the circulation and all of the physiological effects demonstrated in Pola are believed to be simply due to this inherent carnitine uptake by heart tissue. The record does not show or suggest that if the compounds in Pola were used in experiments involving skeletal muscle, there would be a noticeable increase in carnitine uptake into the skeletal muscle.

Bohles et al is a study of the influence of intravenously administered L-carnitine on lipid and nitrogen metabolism in

piglets. The study demonstrates a more effective lipolysis and oxidation of fatty acids during L-carnitine supplementation.

This paper does not make any statement or provide any evidence of an increase in carnitine retention in the skeletal muscle.

Applicant notes that Bohles et al discloses that administration of the carnitine was done under conditions wherein the agent (glucose) that would act to increase insulin concentrate was actually reduced (Period 3), which teaches away from the present claimed subject matter. Table II on page 11 of Bohles et al shows that the level of serum insulin when the carnitine is administered is low (less than half that in Period 1) but the level of serum carnitine remains high. Bohles et al therefore does not disclose or suggest the present claimed subject matter, which aims to increase carnitine retention (i.e. uptake from the blood/plasma) by the co-administration of an agent that positively acts to increase blood/plasma insulin concentration.

Bohles et al is completely silent on the use of insulin to increase carnitine uptake into skeletal muscle. There is no measure of the carnitine concentration in any tissue, and in particular not in skeletal muscle. The authors appear to ascribe their response to carnitine supplement as being to carnitine itself and therefore any metabolic effects are believed to be occurring in the liver and/or the heart, which do not exhibit the carnitine retention difficulties of skeletal muscle.

Gross et al relates entirely to carnitine transport in the small intestine of rodents.

The two main aspects to the study reported in Gross et al were to evaluate the differences in carnitine retention characteristics of rat and guinea pig small intestine and whether elevated lipid oxidation states (fasting and suckling) influenced intestinal carnitine uptake. The latter is perhaps the more relevant aspect. Firstly during the fasted and suckling states i.e. elevated fat oxidation states, the blood/plasma insulin

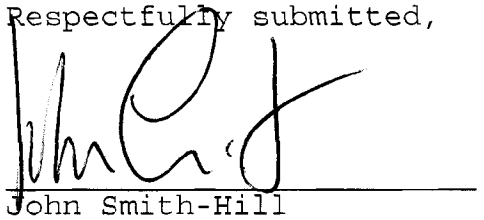
concentration is very low. These studies were therefore carried out under conditions that are in contrast to conditions created by the present claimed subject matter.

There are perhaps two key distinctions between the present claimed subject matter and Gross et al. Firstly, the present claimed subject matter is concerned with carnitine retention in skeletal muscle. Gross et al is concerned with carnitine retention in the intestine. Applicant submits that this difference is very significant.

Second, a key feature of the present claimed subject matter is the provision of an agent to increase blood/plasma insulin concentration, as such an increase results in an increase in carnitine retention in skeletal muscle. There is no suggestion of the effect of increasing insulin concentration on carnitine retention in Gross et al. Indeed, the suggestion is that simple dietary administration of carnitine itself under conditions of very low insulin concentration results in carnitine retention in the intestine.

In view of the foregoing, applicant submits that the subject matter off the independent claims 58, 59, 76 and 93 is not disclosed or suggested by the cited references, whether taken singly or in combination. Therefore, claims 58, 59, 76 and 93 are patentable and it follows that the dependent claims also are patentable.

Respectfully submitted,



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